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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,247	02/14/2002	Paul A. Wender	8400-0013	3262

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
1400 PAGE MILL ROAD
PALO ALTO, CA 94304-1124

EXAMINER

GUDIBANDE, SATYANARAYAN R

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/078,247

Applicant(s)

WENDER ET AL.

Examiner

Satyanarayana R. Gudibande

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,9,10 and 12-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7,8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/24/03, 7/15/04, 8/22/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-35 are pending in the application.

Claims 3, 5, 6, 9, 10 and 12-35 are withdrawn as being drawn to non-elected species.

Claims 1, 2, 4, 7, 8 and 11 are examined on the merit.

The applicant's elected species of the transport moiety (R aca)₆R wherein R is arginine and aca is ε-amino caproic acid and 'n' is 6 is free of art.

Election/Restrictions

Applicant's argument that the Examiner construed the restriction erroneously is partly true. Claims 4 and 11 were elected invention and claims 1, 2, 7-9, 14-26, 28 and 29 were linking claims. It should be noted here that claim 27 also should be grouped along with the other linking claims. As per applicant's argument, claims 4 and 11 should have been included in the rejection and not withdrawn. The MPEP provides a procedure as to examination of species: As an example, in the case of an application with a Markush-type claim drawn to the compound $\text{*} > \text{X} - \text{R} <$, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, $\text{*} > \text{X} \text{A}, \text{X} \text{B}, \text{X} \text{C}, \text{X} \text{D}, \text{or} \text{X} \text{E} <$. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the nonelected species would be held withdrawn from further consideration. $\text{*} > \text{A} <$ second action on the rejected

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claims *>can< be made final >unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a)<.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended to the next species. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action >can be< made final >unless the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). See MPEP § 706.07(a)<.

Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry >if they do not comply with the requirements of 37 CFR 1.116. See MPEP § 714.13 (See **MPEP 803.02**). Examiner had indicated in the previous office action of 3/15/06 that the

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elected species was free of art. Since Examiner found art on a species that is not the elected species and did not read on claims 4 and 11, and did not contain the ϵ -amino caproic acid, therefore, claims 4, 11 and 9 were withdrawn and claim 8 was examined. Claim 27 was inadvertently withdrawn in the office action dated 3/15/06. However, it has been rightly rejected under 35 USC § 103 in our office action dated 3/15/06.

Response to Arguments

Maintained Rejections

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7 and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lorezen, et al., The Journal of Cell Biology, 1995, 131, 631-643.

Applicants argue that the claim rejection should be on claims 1, 2, 4, 7, 9 and 11 and not on 1, 2, 7 and 8 as being anticipated by Lorenzen, et al. The transport compound studied in Lorenzen, et al., is 100 amino acid long and the compound of the present invention wherein the transport moiety is of maximum length of 21-41 amino acids depending on the different species claimed. Applicants further argue that the compounds of Lorenzen were synthesized inside the cell and Examiner has not provided any evidence that these are used as transport molecules.

Applicant's arguments filed on 7/11/06 have been fully considered but they are not persuasive. It should be noted the claim 1 and 4 recites that the transport moiety **comprises** (emphasis added) the structure $(ZY)_mZ$ and hence the length of the amino acid sequence comprising the structure $(ZY)_mZ$ recited in the claim is inconsequential. Since the molecule

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RKRKR of Lorenzen, et al., reads on the structure recited in the claims 1 and 2, it is inherent that the molecule exhibits the desired property as a transport moiety. Therefore, the rejection under 35 USC § 102(b) is maintained.

Withdrawn rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejections of claims 1, 2, 7, 8, 17-19 and 27 under 35 USC § 103(a) has been withdrawn in view of applicant's amendments to the claims.

New grounds of rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsson, et al., Biochimica et Biophysica Acta, 1991, 1097, 37-44.

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In the instant application, applicants claim composition comprising a biological active compound and a transport moiety wherein the transport moiety comprises a structure $(ZY)_mZ$ wherein Z is L- or D- arginine and Y is independently selected from an amino acid that does not comprise an amidino or guanidino group.

Olsson, et al., discloses the peptide RSRSRSRSR, which can be represented as $(RS)_4R$ wherein 'R' is arginine and 'S' is serine. Olsson, et al., studied the association of chondroitin-6-sulfate proteoglycan with low-density lipoprotein (LDL) that is responsible for LDL accumulation during atherogenesis (abstract). Study indicated that RSRSRSRSR was most effective in blocking LDL-chondroitin-6phospahte association. The peptide in association with chondroitin-6-sulfate meets the limitation of claims 1 and 4 which is drawn to a composition comprising of biologically active compound and a transport moiety, wherein the transport moiety comprises a structure consisting of $(ZY)_mZ$ wherein Z is L- or D- arginine and Y is independently selected from an amino acid that does not comprise an amidino or guanidino group. The biologically active molecule in the reference is chondroitin-6-sulfate.

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 7 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by US 7,070,807 B2 issued to Mixson.

In the instant application, applicants claim composition comprising a biological active compound and a transport moiety wherein the transport moiety comprises a structure $(ZY)_mZ$

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wherein Z is L- or D- arginine and Y is independently selected from an amino acid that does not comprise an amidino or guanidino group.

Mixson, discloses transport sequence (RH)₄RG(RH)₄R (SEQ ID No. 13 in column 35) wherein 'R' is arginine and 'H' is histidine, that meets the limitation of claims 2 and 4. It is also disclosed that the arginine-histidine copolymer (Seq ID No. 13) was significantly better at enhancing transfection efficiency (column 24, lines 47-50). The reference also discloses that the transport moiety is inclusive of linear and branched polymers (page 8, lines 30-32). The reference discloses that the pharmaceutical component (biologically active compound of the instant application) interacts with the transport polymer (transport moiety of the instant application) by non-covalent or covalent interactions (column 15, lines 30-44) meeting the limitations of claim 1. In a specific example, Mixson studied a polymer:liposome:DNA complex for the transport efficiency of transport moiety (columns 23 and 24). The liposome was used as a linker, linking the transport moiety and the biologically active molecule DNA. They found that the transport polymer mixed with the DNA and then mixed with the liposome yielded the best transport efficiency and the efficiency was significantly better with use of Seq ID No. 13 a copolymer of arginine and histidine as mentioned earlier. This meets the limitation of claim 7, which requires the transport moiety attached to the biologically active molecule by a linking moiety to form a conjugate. Amino acids arginine, histidine and glycine shown in Seq ID No. 13 are gene encoded amino acids and hence meets the limitations of claim 8.

New Matter Rejection

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 7, 8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 4 have been amended to recite $(ZY)_mZ$ wherein 'm' is an integer from 3-10 in claim 1, 'm' is an integer ranging from 4-10 in claim 4 and 'm' is an integer 6, 7 or 8 in claim 11.

Lack of Ipsis Verbis Support

The specification lacks any *Ipsis Verbis* support for the amendments to the claims as currently claimed. The specification does not support the introduction of the subscript 'm' as recited in amended claims 1, 4 and 11. There is no mention of the transport moiety $(ZY)_mZ$ in the specification.

Lack of implicit support

MPEP § 2163 states that, "[n]ew or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. See, e.g., *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range);

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In re Smith, 458 F.2d 1389,1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).” Further, the MPEP states, “[w]hile there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.”

The claims 1 and 4 recite limitations $(ZY)_mZ$ wherein m is an integer from 3-10 in claim 1, and m is an integer ranging from 4-10 in claim 4. The newly added limitation, the subscript ‘ m ’ lacks implicit inherent support in the disclosure. The specification only discloses the formula $(ZY)_nZ$. Anyone reading the specification could not implicitly derive the formula $(ZY)_mZ$ from specification. Therefore, recitation of $(ZY)_mZ$, where in the subscript ‘ m ’ in the claims constitutes new matter.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

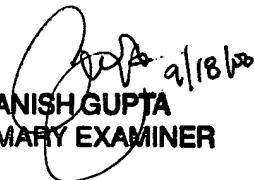
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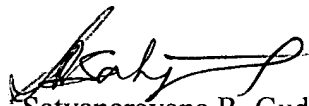
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


ANISH GUPTA
PRIMARY EXAMINER


Satyanarayana R. Gudibande, Ph.D.
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